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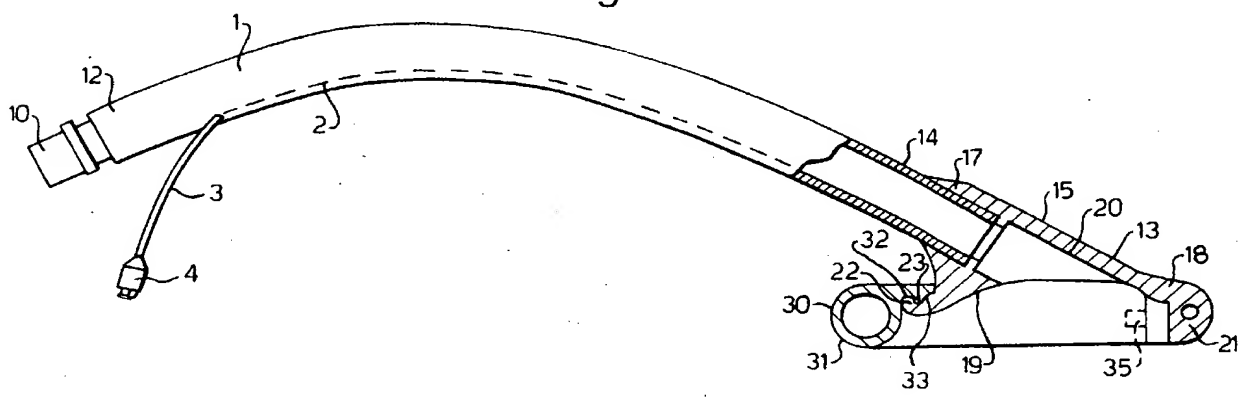
(54) Laryngeal mask airways and their manufacture

(57) A laryngeal mask has a mount 15 at its patient end of elliptical shape supporting an inflatable cuff 30. The cuff 30 is a hollow extruded tube with an integral attachment flange 32 and has opposite ends receiving two spigots 35 on the mount 15. The attachment flange 32 is attached to the mount 15 by means of a projecting tooth 33, which locates in a channel 23 around the mount.

Fig.1.



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Description

This invention relates laryngeal mask assemblies of the kind comprising an elongate tube and a mask portion at the patient end of the tube, the mask portion including a mount member of generally elliptical shape having an opening therethrough communicating with the patient end of the tube.

It is common practice to use an airway known as a laryngeal mask for the administration of anaesthetic and ventilation gases to a patient. These airways comprise a tube with an inflatable mask or cuff at one end, the tube being inserted in the patient's mouth so that one end is located in the hypopharynx and so that the mask forms a seal in this region with the surrounding tissue. Laryngeal masks are described in, for example, US 5355879, US 5305743, US 5297547, US 5282464, GB 2267034, US 5249571, US 5241956, US 5303697, GB 2249959, GB 2111394, EP 448878, US 4995388, GB 2205499, GB 2128561 and GB 2298797.

Laryngeal masks have several advantages over endotracheal tubes, which are longer and seal with the trachea below the vocal folds. It can be difficult, however, to manufacture the patient end of the mask at low cost.

It is an object of the present invention to provide an improved laryngeal mask assembly and method of manufacture.

According to one aspect of the present invention there is provided a laryngeal mask assembly of the above-specified kind, characterised in that the assembly includes a hollow cylindrical cuff member extending around the mount member, and that the cuff member has an attaclunent flange projecting laterally of the cuff member along its length by which the cuff member is attached to the mount member.

The mount member preferably has two spigots, opposite ends of the cuff member being open and mounted on respective ones of the spigots. At least one of the spigots preferably communicates with an inflation lumen extending along the tube so that the cuff member can be inflated via the lumen and a spigot. The attachment flange of the cuff member may have a projecting member extending along its length defining a channel between the projecting member and a tubular portion of the cuff member. The mount member may have a channel extending around its outer edge, the projecting member on the attachment flange being located in the channel on the mount member. Alternatively, the attachment flange may be of arrow shape in section.

According to another aspect of the present invention there is provided a method of manufacture of a laryngeal mask assembly including the steps of providing an elongate tube having a mount member at its patient end, the mount member being of generally elliptical shape and having an opening therethrough communicating with the patient end of the tube, providing a hollow cylindrical cuff member having an attachment flange projecting laterally along its length, folding the cuff member about an outer edge of the mount member, and attaching the attachment flange to the mount member.

The cuff member is preferably extruded.

A laryngeal mask airway assembly and its method of manufacture, according to the present invention, will now be described, by way of example, with reference to the accompanying drawings, in which:

Figure 1 is a partly-sectional side elevation view of the assembly;

Figure 2 is an underside view of the patient end of the assembly;

Figure 3 is a transverse cross-side view, to an enlarged scale, of the cuff; and

Figure 4 is a transverse cross-side view, to an enlarged scale, of an alternative cuff.

With reference to Figures 1 to 3, the assembly comprises a bendable tube 1 of a plastics material, such as PVC, with a coupling 10 at its machine end 12. The tube 1 is curved along its length and has a mask portion 13 at its patient end 14.

The tube 1 is extruded with an inflation lumen 2 within its wall. The lumen 2 is connected towards the machine end of the assembly to an inflation line 3 with an inflation indicator and connector 4. The opposite, patient end of the inflation lumen 2 communicates with the mask portion 13.

The mask portion 13 includes a mount member 15 moulded from a relatively stiff plastics material, such as PVC. The mount member 15 has a hollow cylindrical sleeve 17 at its rear end, in which the forward, patient end 14 of the tube 1 is inserted and joined. The forward, patient end 18 of the mount member 15 is of an inverted dish shape with a generally elliptical or egg-shape outline and with a concave recess 19. A bore 20 extends forwardly through the mount member 15, as a continuation of the bore through the sleeve 17, and opens into the rear part of the recess 19. The forward surface of the mount member 15 has a projection 21 of inverted V-shape at its forward tip, the purpose of which will become apparent later. The rear surface of the mount member 15 has an upwardly-projecting lip 22 extending around the major part of its periphery and, within the lip, a recessed channel 23.

The mask portion 13 also includes an inflatable cuff 30 attached around the edge of the mount member 15. The cuff 30 is extruded from a flexible, resilient plastics material, such as PVC, polyurethane, silicone, EVA, TPE, polyether block amide or the like. The main part of the cuff 30 is provided by a tubular portion 31 of circular section. The cuff 30 also has an integral flange or attachment member 32 projecting laterally outwardly from the tubular portion 31 along its length. The outer end of the flange 32 has a downwardly-projecting tooth 33,

which defines a channel 34 along the underside of the flange, between the tubular portion 31 and an inner edge of the tooth. The cuff 30 could be made by other techniques such as pulsed (bubble) extrusion or blow moulding, or by a combination of extrusion and subsequent blow moulding to produce regions of reduced wall thickness and different diameters. The cuff 30 is folded around the outer edge of the mount member 15, with its flange 32 projecting inwardly and overlapping the outer edge of the mount member. In particular, the tooth 33 on the flange 32 locates in the channel 23 in the mount member 15, and the lip 22 on the mount member locates in the channel 34 on the flange. Opposite ends of the cuff 30 are fitted over two spigots 35 protruding from opposite arms the projection 21 on the mount member 15. A solvent, adhesive or heat bond is used to join the contacting surfaces of the cuff 30 and mount member 15 to one another.

The cuff 30 can be inflated and deflated in various different ways. For example, the projection 21 and spigots 35 could be hollow and communicate with the inflation lumen 2 via a gas passage formed in the mount member 15, so that gas can be supplied to or from opposite ends of the cuff 30. Alternatively, a separate small-bore tube could be connected between the inflation lumen and the interior of the cuff.

The cuff could have various different sections, thus controlling the shape of the cuff when deflated by the application of a vacuum, for insertion into the patient. For example, as shown in Figure 4, the cuff 30' has a flange 32' of arrow-head shape with two oppositely-projecting teeth 33'. This flange 32' can be a snap fit into a recess (not shown) in the mount member of a corresponding shape. The ends of the cuff need not be joined at the tip of the mount member but could instead be joined at the opposite end or heel.

The cuff could be filled with a foam to make it self-inflating and negative pressure applied via the lumen 2 to suck down the cuff for insertion and removal.

Claims

1. A laryngeal mask assembly comprising an elongate tube (1) and a mask portion (13) at the patient end (14) of the tube, the mask portion (13) including a mount member (15) of generally elliptical shape having an opening (20) therethrough communicating with the patient end of the tube, characterised in that the assembly includes a hollow cylindrical cuff member (30, 30') extending around the mount member (15), and that the cuff member (30, 30') has an attachment flange (32,32') projecting laterally of the cuff member along its length by which the cuff member is attached to the mount member.

2. A laryngeal mask assembly according to Claim 1, characterised in that the mount member (15) has two spigots (35), and that opposite ends of the cuff member (30) are open and mounted on respective ones of the spigots (35).

3. A laryngeal mask assembly according to Claim 2, characterised in that at least one of the spigots (35) communicates with an inflation lumen (2) extending along the tube (1) so that the cuff member (30) can be inflated via the lumen and a spigot.

4. A laryngeal mask assembly according to any one of the preceding claims, characterised in that the attachment flange (32) of the cuff member (30) has a projecting member (33) extending along its length defining a channel (34) between it and a tubular portion (31) of the cuff member.

5. A laryngeal mask assembly according to Claim 4, characterised in that the mount member (15) has a channel (23) extending around its outer edge, and that the projecting member (33) on the attachment flange (32) is located in the channel (23) on the mount member (15).

6. A laryngeal mask assembly accorcling to any one of Claims 1 to 3, characterised in that the attachment flange (32') is of arrow shape in section.

7. A method of manufacture of a laryngeal mask assembly including the steps of providing an elongate tube (1) having a mount member (15) at its patient end (14), the mount member being of generally elliptical shape and having an opening (20) therethrough communicating with the patient end of the tube, providing a hollow cylindrical cuff member (30, 30') having an attachment flange (32, 32') projecting laterally along its length, folding the cuff member (30, 30') about an outer edge of the mount member (15), and attaching the attachment flange (32, 32') to the mount member.

8. A method according to Claim 7, characterised in that the cuff member (30, 30') is extruded.

Fig.1.

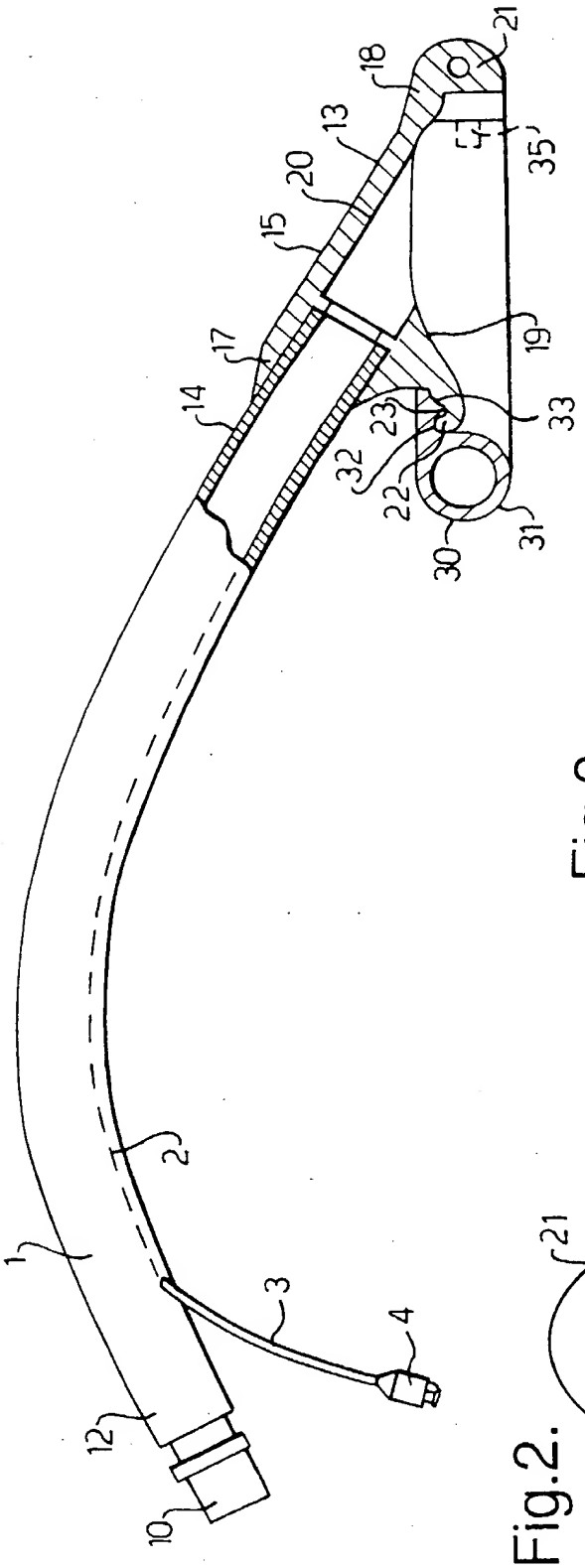


Fig.2.

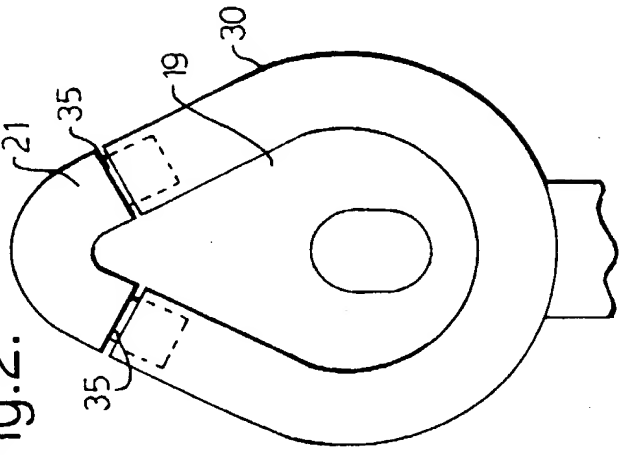


Fig.3.

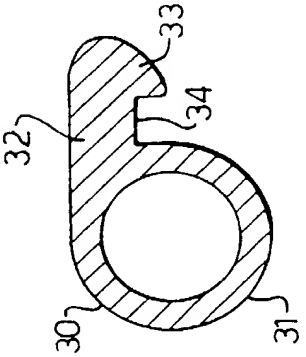
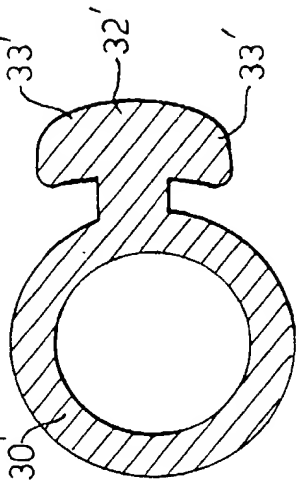


Fig.4.



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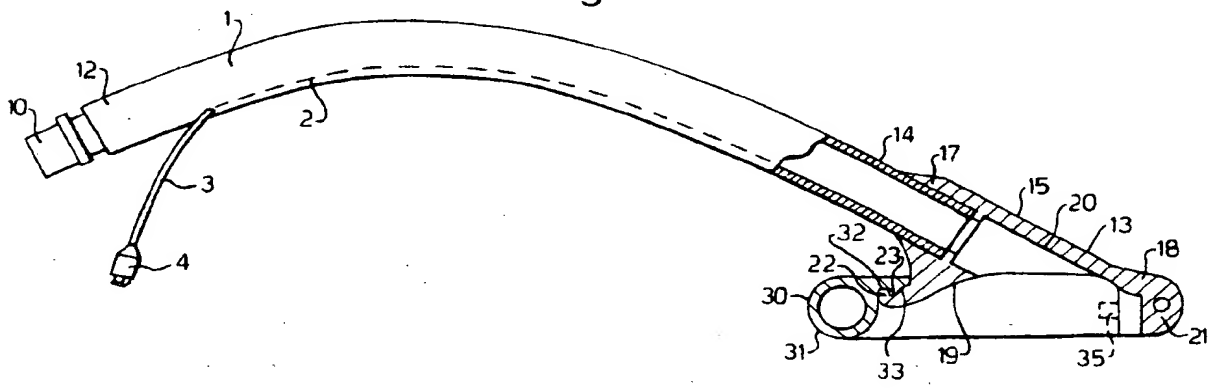

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EUROPEAN SEARCH REPORT

Application Number
EP 98 30 0072

DOCUMENTS CONSIDERED TO BE RELEVANT

Category	Citation of document with indication, where appropriate, of relevant passages	Relevant to claim	CLASSIFICATION OF THE APPLICATION (Int.Cl.6)
A	US 5 282 464 A (BRAIN) 1 February 1994 (1994-02-01) * column 4, line 56 - column 5, line 7; figures 1-6 *	1	A61M16/04
A	EP 0 732 116 A (PAGAN) 18 September 1996 (1996-09-18) * column 2, line 35 - column 3, line 13; figures 1,2 *	1	

TECHNICAL FIELDS SEARCHED (Int.Cl.6)

A61M

The present search report has been drawn up for all claims

Place of search	Date of completion of the search	Examiner
MUNICH	11 February 2000	Germano, A

CATEGORY OF CITED DOCUMENTS

X : particularly relevant if taken alone
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